REMARKS

Claims 1, 2, 5-11, 13-17, 20-23, and 25-29 are pending in the present application. Claims 9, 23, and 27-29 have been withdrawn. Claims 1 and 15 have been amended. The amendment is supported by at least paragraph [0009] of the specification. No new matter has been added to the application. Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the following remarks, which follow the order set forth in the Office Action.

Rejections under 35 U.S.C. §103

Claims 1, 2, 5-7, 12-22, and 24-26 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Sachdeva et al., U.S. Patent No. 5,885,258, ("Sachdeva") in view of Jones, U.S. Patent No. 5,843,050 ("Jones"). Applicants respectfully traverse. Applicants initially note that claims 12, 18, 19, and 24 were previously cancelled, thus the rejection of these claims is moot. Additionally, Applicants note that claim 8 was not specifically addressed in the Office Action. Applicants remarks have been drafted with the assumption that claim 8 was intended to be included in the above §103 rejection. If this understanding is incorrect, please advise.

The cannulas of pending independent claims 1 and 15 include a distal portion comprising a spiral cut extending through an external surface of the distal portion and along a longitudinal axis of the cannula wherein the cannula (or the proximal and distal portions in claim 15) is defined from a continuum of material (or metal in claim 15) and a tool disposed proximate the distal portion that is defined from the continuum of material. As indicated, the spiral cut along the longitudinal axis of the cannula is made in the single continuum of material that defines the cannula and the tool.

The Office Action states that it would have been obvious to one of ordinary skill in the art to incorporate the spiral cut of Jones into the distal portion of the cannula of Sachdeva to impart greater flexibility thereto. *See* OA, page 4. Applicants submit that one of ordinary skill in the art would have no expectation of success in combining the teachings of Sachdeva and Jones. Thus, one of ordinary skill in the art would have no reason to make the above proposed modification to Sachdeva in view of Jones without improper hindsight reference to the instant application. Additionally, Applicants further submit that even if, *arguendo*, the spiral cut of Jones were incorporated into the medical instrument of Sachdeva, the resulting device would not have all of the required limitations of claims 1 and 15.

Sachdeva discloses a medical instrument comprising a memory metal tube **11** with a plurality of slots **12** formed therein at or near a distal end thereof. The plurality of slots **12** form a tool that may be used for various medical procedures. Sachdeva's tube is formed from a material with shape metal properties to allow the tool to be manipulated between extended and restricted positions (as best viewed in FIGS. 1A-1D) both with an external delivery tube **13** that can selectively compress or release the arms of the tool, and due to changes in temperature of the arms of the tool, which causes a change in the orientation of the arms of Sachdeva's tube **11** due to the intrinsic shape memory properties of the material forming the tool. *See* col. 2, ll. 22-41. For example, the memory effect may be used by heating or cooling the plurality of slots **12** through pumping of liquid of an appropriate temperature through the metal tube **11** to the slots **12**. *See* col. 3, ll. 46-50. When the delivery tube **13** is in covering relation to the slots **12**, shape changes in the slots **12** are prevented, such as when the instrument is being inserted into the human body, and when the delivery tube **13** is slid away from the slots **12**, they return to their preprogrammed shape. *See* col. 2, ll. 30-40.

The Sachdeva medical instrument includes three distinct embodiments with regard to the delivery tube: a first embodiment wherein no delivery tube is present (*See* col. 3, ll. 46-50), a second embodiment wherein the delivery tube **13** extends for only the length needed to cover the slots **12** (*See* FIGS. 1-4), and a third embodiment wherein the delivery tube **103** extends for a greater distance along the length of the memory metal tube **101** (*See* FIGS. 10A-C). As indicated above, in embodiments including the delivery tube **13, 103**, the delivery tube **13, 103** must be of sufficient rigidity and strength to control the shape of the slots of the metal tube **11, 101** and prevent shape changes at undesired moments. *See* col. 2, ll. 33-35. Given these embodiments, the primary exterior surface of the Sachdeva instrument is provided by either the metal tube **11, 101**, i.e., in embodiments with no delivery tube or with a relatively short delivery tube, or the delivery tube **103** provides the primary exterior surface of the instrument, i.e., in embodiments wherein the delivery tube extends for a greater distance along the length of the metal tube.

Jones discloses a microcatheter **10** formed from a composite of a series of concentrically arranged tubular elements, each extending axially for a different distance along the tubular body. *See* Abstract. The Jones catheter is particularly directed to navigating the tortuous pathways in soft tissues, such as the brain and liver. *See* col. 1, ll. 5-8. Given this

intended use, the Jones catheter is designed to exhibit optimal flexibility while maintaining adequate column strength. *See* col. 1, ll. 24-25 and col. 1, ll. 42-52.

As shown in FIG. 2, the microcatheter **10** comprises, from inside to outside, a tubular element **30**, a coil spring **34**, a tubular jacket **38**, and an outer tubular jacket **42**. Each of the tubular elements extends axially from the proximal end of the catheter **10** for a predetermined distance in the distal direction, with each of the tubular elements extending a different distance. *See* FIG. 3. The tubular element **30** extends from the proximal end of the catheter for most of the length of the catheter and includes a distal spiral cut section 32 for adding flexibility to this area of the tubular element **30**. *See* col. 5, ll. 19-20. The coil spring **34** extends from the proximal end of the catheter in a distal direction for at least 100 cm. *See* col. 5, ll. 41-43. The tubular jacket **38** extends from the proximal end of the catheter **10** in a distal direction for approximately 90-125 cm. *See* col. 6, ll. 18-19. A distal section **40** of the tubular jacket includes a spiral cut to modify the flexibility properties of the microcatheter **10**. *See* col. 6, ll. 25-27. The outer tubular jacket **42** preferably extends throughout the length of the catheter **10**, beyond the tubular element **30**, to provide a smooth exterior surface. *See* col. 6, ll. 37-39. The catheter **10** is constructed in the described way in order to create a series of zones of relatively increasing flexibility from the proximal end to the distal end of the catheter **10**. *See* col. 6, ll. 52-53. As disclosed, the tubular elements with their particular physical properties and in the particularly disclosed arrangement work synergistically to result in the disclosed device, which is designed to provide optimal flexibility for use in navigating the tortuous pathways in soft tissues.

As indicated above, Jones only discloses including a spiral cut on internal tubular elements. Further, Jones discloses that it is preferred that the catheter be covered with an outer tubular jacket of relatively smooth material for providing a smooth exterior surface and to form a catheter that allows fluid to be delivered to a targeted location proximate the distal end of Jones' device. *See* col. 1, ll. 33-43; col. 3, ll. 5-9. Thus, based on the disclosure of Jones, one would not have any reason to provide a spiral cut in a tubular element that provides the exterior surface of an instrument, because doing so would destroy the purpose of Jones' outer tubular jacket **42**.

Accordingly, given the disclosures of Sachdeva and Jones, one of ordinary skill in the art would either: i) not be motivated to provide a spiral cut in a tubular element of Sachdeva because such combination would be contrary to the teaching of Jones or because such person would have no expectation of success or ii) provide a spiral cut in a tubular element of the

instrument of Sachdeva to result in a device that does not have all of the required limitations of the cannulas of claims 1 and 15. Either way, the inventions of claims 1 and 15 are not obvious in view of the combination of Sachdeva and Jones.

For organizational purposes, the below remarks are arranged according to the three above-described embodiments of the Sachdeva instrument.

A) Instrument having no delivery tube

For this embodiment, the instrument either has a single memory metal tube **11** (FIGS. 1A-D) or the instrument has a memory metal tube **101** and interior tubes **107, 108** (FIGS. 10A-C). For any of these instruments, the memory metal tube **11, 101** provides the exterior surface of the instrument. Thus, based on the disclosure of Jones, one of ordinary skill in the art would not make a spiral cut in the memory metal tube **11, 101** because to do so would be contrary to the teaching of Jones. Alternatively, for the instruments having interior tubes **107, 108**, potentially, a spiral cut may be made in these interior tubes **107, 108**. However, providing a spiral cut in these interior tubes **107, 108** would not result in a device that has all of the required limitations of claims 1 and 15. Claims 1 and 15 require that the spiral cut be made in the continuum of material that defines the cannula and the tool. The interior tubes **107, 108** are not a part of a continuum of material that defines a tool of the instrument. Thus, the Sachdeva instrument having a spiral cut in the interior tubes **107, 108** thereof does not have all of the required limitations of claims 1 and 15.

B) Instrument wherein the delivery tube is relatively short, i.e., only long enough to cover the slots of the metal tube

The analysis of the so-called second embodiment is essentially the same as that for the so-called first embodiment because the metal tube **11, 101** also provides the exterior surface of the instrument in this embodiment. As indicated above, one of ordinary skill in the art would not make a spiral cut in the exterior surface of the Sachdeva instrument based on the teaching of Jones because to do so would be contrary to the teaching of Jones. As also indicated above, providing a spiral cut in the interior tubes **107, 108** of a Sachdeva instrument having such interior tubes **107, 108** would not result in a device that has all of the required limitations of claims 1 and 15.

C) Embodiment wherein the delivery tube extends a greater distance along the length of the metal tube

For this embodiment, as with the above embodiments, one of ordinary skill in the art would not have a reason to modify Sachdeva to provide a spiral cut in the delivery tube **103** of the instrument because the delivery tube **103** provides the exterior surface of the

instrument and providing a spiral cut in the exterior surface of the instrument is contrary to the teaching of Jones.

With regard to the internal tubes **101, 107, 108** of this embodiment, Applicants submit that one of ordinary skill in the art would have no reason to provide a spiral cut in the internal tubes because there would be no expectation of success in doing so. The Office Action states that the motivation for combining the spiral cut of Jones with the instrument of Sachdeva is to provide a high degree of flexibility to the instrument to facilitate negotiation of small, tortuous vessels. However, Applicants submit that providing a spiral cut in the internal tubes **101, 107, 108** would have no appreciable effect on the flexibility of the instrument. As indicated previously, the metal tube **101** and thus the slotted section **102** of the metal tube are constructed of memory metal. As also indicated previously, the delivery tube **103** must be constructed of a material that is sufficiently rigid and strong to control the shape of the slotted section **102** and prevent shape changes of the slotted section **102** at undesired moments, such as during the procedure of insertion into the human body. Thus, the delivery tube **103** necessarily has relatively high rigidity and strength. As such, one of ordinary skill in art would not be motivated to provide a spiral cut in the metal tube **101** (or any other internal tube) of the Sachdeva instrument in order to provide a high degree flexibility thereto because even if the spiral cut provided a high degree of flexibility to the internal tube **101**, such increased flexibility of the internal tube **101** would not result in a high degree of flexibility for the corresponding area of the instrument as a whole because the rigidity of the delivery tube **103** would govern the flexibility of the instrument. There would be no benefit to having an internal tube **101** with an increased area of flexibility if the increased flexibility was not imparted to the instrument as a whole. As such, one of ordinary skill in the art would have no reason to modify the Sachdeva instrument as proposed by the Office Action because he would have no expectation of success. Given this fact, any combination of these references would be done based on improper hindsight reference to the instant application.

Based on the foregoing, Applicants submit that the inventions of claims 1 and 15 are not obvious in view of the combination of Sachdeva and Jones. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

For the foregoing reasons, claims 1 and 15 and claims 2, 5-8, 10-11, 13-17, 20-22, and 25-26, which depend therefrom, are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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